

Substandard and falsified medical products are a global public health threat. A pilot survey of awareness among physicians in Sweden

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ABSTRACT

Background Substandard and falsified medical products are a public health threat, primarily associated with low- and middle-income countries. Today, the phenomenon also exists in high-income countries. Increased Internet access has opened a global market. Self-diagnosis and self-prescription have boosted the market for unregulated websites with access to falsified medicines.

Aim To describe the state of knowledge and experience on SF medical products among emergency physicians (EPs) and general practitioners (GPs) in Sweden.

Methods An online survey with anonymous answers from 100 EPs and 100 GPs. Physicians were recruited from TNS SIFO's medical database. The term in the survey was 'illegal and falsified medicines' which was common in Sweden at that time. It corresponds well with the term 'substandard and falsified medical products' that the WHO launched shortly after our data collection. We report our results with this term.

Results In Sweden, 78.5% of the physicians had heard the term 'illegal and falsified medicines' and 36.5% had met patients they suspected had taken it. Physicians lacked awareness of the use of the reporting system and wanted more knowledge about how to deal with patients who have possibly used falsified medicines.

Conclusions To meet the public health threat of SF medical products, physicians need more knowledge.

Keywords drug abuse, emergency care, primary care

Introduction

The spread of substandard and falsified medical products is a public health threat.¹ Due to the low level of knowledge about its scope and consequences, however, legal regulations and penalties differ widely globally.² Similarly, the definition differs as to what is a spurious medical product. In May 2017, the World Health Organization (WHO) presented a working definition aimed at specifying what may fall within the scope of spurious medical products. WHO states that medical products are to be referred to as substandard and falsified (SF) medical products; *substandard* if they are 'authorized medical products that fail to meet either their quality standards or specifications, or both', whereas *falsified*

medical products are 'medical products that deliberately/fraudulently misrepresent their identity, composition or source'.³ In this article, we follow WHO's definition of SF medical products.

SF medical products can contain no active ingredient, an inappropriate level of the active ingredient, or substances inappropriate to consume.⁴ The direct danger is often the lack of efficiency making them incapable of curing the

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disease.¹ The consequences are expected to be drug resistance and lack of confidence in healthcare.^{5,6} In addition to the problems associated with ineffective drugs, falsified products sometimes contain toxic substances that can lead to disability or death.¹ According to WHO, both lifesaving and lifestyle medicines, generic and branded medicines, are targeted by falsifiers.^{7,8}

SF medical products have primarily been associated with low- and middle-income countries, but today the phenomenon also exists in high-income countries. The increased Internet access has opened a global market.⁹ In many places, such as in Europe and the USA, this seems to coincide with a reorientation of the individual's relationship with healthcare system, and with the broader welfare state. A shift in responsibility from the state to the individual has eroded trust in the system and has led to a rise in self-care practices. In Sweden, for example, much indicates that people are increasingly looking for information about medicines on the Internet, for example by asking other Internet users for advice, instead of turning to doctors and pharmacies.^{10–13} As people's attitudes to taking care of themselves have changed, and trust in authorities has diminished, the Internet has taken the place as a site for health knowledge exchange and the circulation of healthcare commodities, such as medicines. This culture of self-diagnosis and self-prescription has boosted the market for unregulated websites with access to SF medical products.^{9–13} The controlled supply chain for medicines between production and patients is long and complex.^{14,15} Any weak link may enable the entrance of SF medical products. In all regions of the world, SF medical products have entered hospitals, clinics and pharmacies, although SF medical products are more common on the illegal market.¹⁵ SF medical products are by nature hard to detect. The scope is based on estimations. Since there is little validated data to underpin estimations of the scope, scale and harm, the WHO in 2013 launched a global surveillance and monitoring system.¹⁶ Africa accounts for the largest number of reports to WHO.¹⁷ The system, however, is under-reported and research shows that reports do not correspond to the actual situation in other regions such as Asia.¹⁸ Fairly few reports exist from Europe¹⁷ of which two are from Sweden.¹⁹ However, the problem is seen as very serious by the Swedish Medical Products Agency (MPA). In order to find out Swedish citizens' views of online medicines, MPA conducted an online survey in 2014 asking 2000 persons, randomized and representative for the public, about their experiences of buying prescription-only medicines online without prescription. Only a few percent had done it but 40% were considering doing so in the future. Over-represented groups were younger people and people from urban environments.²⁰

In addition, the Swedish MPA informs healthcare staff about treatment recommendations. A published manual and a website give guidelines on how doctors should act if SF medical products are suspected. Healthcare staff should be aware of and actively ask for a possible use of SF medical products, primarily ordered online. Physicians are recommended to advise patients not to buy medicines on illegal websites and report any suspicion of adverse effects of medicines, including SF medical products.²¹

Aim

This study was conducted as a part of the interdisciplinary project "Illegal drugs—information gathering from the general public and physicians. A study for implementing knowledge in society". The project is a collaboration between the Department of Arts and Cultural Science at the Faculties of Humanities and Theology and the Faculty of Medicine at Lund University, Sweden.²² The study is specifically aimed at collecting data within the Swedish healthcare regarding SF medical products.

In order to identify the scholarly knowledge regarding SF medical products as well as gaps in the literature, researchers in the project conducted a preliminary study in the form of a literature review.²³ With coded keywords, a search for academic journals published between 2000 and 2015 within all the databases Lund University subscribes on the EBSCOhost database platform was conducted. One identified gap is an absence of empirical studies of the knowledge of SF medical products among doctors and health staff, and how they follow-up patients with unusual lack of medical efficacy or unfamiliar medical side effects. We assumed that physicians working in the first line on the healthcare as emergency physicians (EPs) and general practitioners (GPs) would be most exposed to the problem. Therefore, the aim of this study was to gather information that could form a basis to describe the state of knowledge and experience on SF medical products among EPs and GPs.

Methods

We chose a survey with some questions with a mixed format of multiple-choice and open-ended questions. In the survey, we addressed the problem as 'illegal and falsified medicines', which was the most common term used in Sweden at the time of our survey in 2016. Over the years, there have been a variety of definitions world wide of the phenomenon.² This has complicated collaborations and discussions and is one of the reasons why the WHO in 2017 proposed the standardized term 'substandard and falsified medical

products' (SF medical products).³ Although there are still different opinions in the science communities, SF medical products is the most internationally recognized term. It was introduced the year after our survey while we were compiling our data. In order to place our study within the framework of ongoing discussions globally we chose to report the results using the term SF medical products. The survey is displayed in the Appendix. The quantitative analysis included descriptive statistics of the multiple-choice questions. The content of open-ended questions was categorized. No comparison of the EPs and the GPs was made since it was not the purpose of the study.

The survey was constructed as an online survey with anonymous answers from 100 specialists working as GPs and 100 specialists working as EPs. The answers were collected and presented to the research group by TNS SIFO, an established Swedish market research institute. Physicians were randomized and recruited from TNS SIFO's medical database. The medical database was built in 1985 and was based on a commercial list of Swedish licensed physicians. Physicians serving abroad, not entering their workplace address or blocking their data are not included in this list. Once the database was created TNS SIFO made the updates themselves in order to ensure its relevancy. It is continually updated to reflect the current treating physicians. The database is not self-recruited.²⁴

The respondents were recruited via e-mail. After recruitment, a link with the questionnaire was sent to the respondents. The physicians were introduced to the subject with written information and answered online. To receive 100 answers from GPs, 260 GPs were randomly selected from TNS SIFO's medical database. The GPs were invited to participate and the study closed after having obtained the first 100 answers. To receive 100 answers from physicians working with emergency care, 900 physicians were randomly selected from TNS SIFO's medical database. To participate in the survey, the physicians had to confirm that they worked in emergency medicine, thus excluding 74. The study was closed after the first 100 answers were received from EPs. Physicians from different medical specialties work in emergency care in Sweden and the sample consisted of 37 internal medicine specialists, 25 psychiatrists, 18 lung specialists, 15 infection specialists, 1 surgeon, 1 specialist in emergency geriatrics, 1 anesthesiologist, 1 specialist in emergency medicine and 1 specialist in general practice. The answers were collected during May–June 2016.

Ethics

The survey study has been approved by the Regional Ethical Review Board in Lund, registration number 2016/238.

Results

Survey background information

The group of EPs consisted of 68 males and 32 females with a median age of 58 years. The group of GPs consisted of 60 males and 40 females. Their median age was 60 years.

Survey results

Knowledge of the term

About four-fifths of the respondents (157/200) had heard of the term 'illegal and falsified medicines' (reported here as substandard and falsified medicines as explained above) before participating in the survey. Among those who knew the term, the leading source was media (137/157) such as daily newspapers (96/137), medical journals (84/137) and television (76/137). Other major sources were patient-related events at work (50/157) and colleagues (48/157) (Table 1).

Meeting patients and suspecting SF medical products

Thirty-eight EPs and 35 GPs had personally met patients who were suspected to have taken SF medical products. In a free comment, EPs mentioned clues evenly from the medical history and patients' symptoms (21 vs. 17), while GPs mainly received clues from the medical history (27 vs. 8). Some comments hinted about the type of medicines they suspected. The most common medicines were opioids and benzodiazepines (14) followed by anabolic steroids (7). Single comments also mentioned erectile dysfunction medicine (2), treatment for hepatitis C (1), antibiotics (1) and health products (1). In 47 comments, it was not possible to specify what type of medicines was implied. Eleven comments mentioned ordering online.

The informants were asked in an open-ended question how they would act if they had a strong suspicion their patient was taking SF medical products (Table 2). A majority (129) gave answers that could be seen as trying to influence the patients' opinion and 10 physicians mentioned the possibility of reporting to the Swedish Medical Products Agency. Thirteen physicians gave an answer that might lead them to more knowledge on how to act, mainly by talking to another person within healthcare.

Unfamiliar medicines

A majority of the physicians (137) had encountered medicines they did not recognize (Table 3). More than half (78/137) were specified as foreign pharmaceuticals. The most common types of medicines were antibiotics (33/137), analgesics and NSAID (126/137), cardiovascular medicines (19/137) and sedative and hypnotic medicines (13/137). Most patients obtained the unfamiliar medicine abroad

Table 1 Physicians' knowledge of the term 'illegal and falsified medicines'

	<i>EPs</i>		<i>GPs</i>	
	(<i>n</i> = 100)	(%)	(<i>n</i> = 100)	(%)
Having knowledge of the term 'illegal and falsified medicines'	73	73	84	84
Type of source:	(<i>n</i> = 73)	(%)	(<i>n</i> = 84)	(%)
Media	62	85	75	89
Patient-related events at work	25	34	25	30
Colleagues	29	44	19	18
Private contacts	10	14	7	8
Others	5	5	5	6
Type of media:	(<i>n</i> = 62)	(%)	(<i>n</i> = 75)	(%)
Daily newspaper	46	74	50	67
Medical journal	37	60	47	63
TV	33	53	43	57
Social media	7	11	11	15
Others	6	10	2	3

Table 2 How physicians would act if suspecting that a patient takes SF medical products

	<i>EPs</i> (<i>n</i> = 100)	<i>GPs</i> (<i>n</i> = 100)
Inform the patient about the risks/talk with the patient	62	67
Advise against the use	21	14
Contact/report to different authorities, including the Medical Products Agency	14	5
Talk to colleagues/my manager	8	6
Take drug test/urine/send the drug for analysis	10	3
Issue new recipe/give the right medicine	8	3
Asks the patient to report to the police	4	4
Have not met any patient where there have been suspicions of SF medical products	2	5
Other	15	8
Do not know	4	6

(105/139), or on the Internet (22/137). Common ways for the physicians to act were to try to identify the medicine (56/137), inform the patient about risks or counseling (42/137) and to discourage the patient from the treatment (23/137).

The need for more knowledge

A majority of the physicians (157/200) expressed a need more knowledge about SF medical products. In descending order they favored written material such as newspaper articles and guidelines (109/157), lectures (76/157), or online education (62/157) (Table 4).

In the open-ended questions of the survey, some physicians addressed this want. One respondent wrote about the difficulty of knowing what happens outside the regulated

medical system and stated, 'I answer questions at the health-care counseling hotline and it seems that some of them [laypersons] use [prescription-only] medicines they received in other ways than by prescription from a physician'. Another respondent pointed out the lack of knowledge of SF medical products and emphasized that 'the biggest issue is probably that we are unaware of the scenario that patients might have bought medicines this way [abroad or on the Internet]'. Other respondents stressed the importance of learning more about the problem and said that 'it is frightening that an unregulated online market exists with both potent and ineffective medicines'. The statements provide some examples and point to a number of problems that may arise in the wake of a growing unregulated medical market.

Table 3 Patients with medicines unfamiliar to the physicians

	<i>EPs</i>		<i>GPs</i>	
	(<i>n</i> = 100)	(%)	(<i>n</i> = 100)	(%)
Physicians who had met patients with unfamiliar medicines	68	68	69	69
Type of medicines	(<i>n</i> = 68)	(%)	(<i>n</i> = 69)	(%)
Foreign pharmaceuticals	28	41	50	72
Antibiotics	13	19	20	29
Analgesics and antiphlogistics	13	19	13	19
Cardiovascular medicines	9	13	12	17
Sedative and hypnotic medicines	10	15	3	4
Vitamins, herbal remedies and health products	6	9	6	9
Other	21	31	18	26
Do not know	3	4	1	1
How the medicines were received	(<i>n</i> = 68)	(%)	(<i>n</i> = 69)	(%)
By doctor or pharmacy abroad	24	35	29	42
Abroad, unspecified	22	32	22	32
Internet	14	21	8	12
Doctor or pharmacist	4	6	7	10
Abroad in a store that was not a pharmacy	5	7	3	4
Other	10	15	7	10
Do not know	4	6	0	0
How physicians acted	(<i>n</i> = 68)	(%)	(<i>n</i> = 69)	(%)
Searched/googled/called the pharmacy to find out what kind of medicine it was	24	35	32	46
Informed the patient about the risk and counseling	21	31	21	30
Discouraged the patient from the treatment/medicines	13	19	10	14
Prescribed/change to the right medicine	8	12	12	17
Documented/recorded in the medical record	4	6	1	1
Recommended disposal of the medicines by the pharmacist	3	4	2	3
Other	5	7	4	6
Do not know	3	4	3	4

Table 4 Physicians' opinions on the need for more knowledge

	<i>EPs</i>		<i>GPs</i>	
	(<i>n</i> = 100)	(%)	(<i>n</i> = 100)	(%)
Physicians who need more knowledge about SF medical products				
Yes	81	81	76	76
No	19	19	24	24
How physicians would like to obtain more knowledge	(<i>n</i> = 81)	(%)	(<i>n</i> = 76)	(%)
Written material (newspaper articles, guidelines etc.)	56	69	53	70
Lectures	45	56	31	41
Education online	32	40	30	39
Group discussions	8	10	7	9
In other way	2	2	2	3

Discussion

Main findings of this study

This pilot study shows that a majority, but not all, of physicians in emergency rooms and general practice were aware the term SF medical products but few had knowledge of guidelines including the appropriate use of the reporting system. A need for more education was expressed by the physicians.

In this survey study, 21.5% of the participating physicians had not heard the term SF medical products and the leading source of information for those who had was the media. The survey did not contain any information alternative such as education or information from healthcare or authorities. The participants could give this answer under 'other source', an alternative selected by 10 of 157 physicians where this type of source was the main source. Even if it is underestimated, the number is far from the 137 physicians that gained knowledge of the term from the media.

It is obvious from the results that a majority of the EPs and the GPs were not familiar with current recommendations on actions when SF medical products are suspected. The answers on how the physicians would act if they had a strong suspicion their patient was taking SF medical products were compared with the recommendations from the Swedish MPA. In accordance with the recommendations a large proportion, 129 out of 200, mentioned conducting advocacy work. However, many physicians did not mention this. One possibility is that advising against the use of medicines of unwarranted quality is so obvious that the physicians did not even think of mentioning it in the survey. Only 10 out of 200 physicians answered that they would report a strong suspicion of SF medical products to the MPA, although this is recommended at any suspicion of an adverse event. There is thus a potential for improvement when it comes to communicating the issue of SF medical products from the authorities to the treating physicians, including the use of the reporting system.

The results show that EPs met more patients where the patients' symptoms led to suspicion. This is expected because of the different patient clientele between emergency and primary care.

In the survey, 78.5% were positive to the idea of gaining more knowledge about SF medical products. The participants wanted to obtain information from written material (newspaper articles, guidelines etc.) followed by lectures or education online. Some written material exists,^{21,25} but there might be a need for improvement of communicating the written material to the physicians. The topic has received little public interest in the media, which is also an important source of information for physicians.

What is already known of this topic?

There is little knowledge about physicians' awareness of SF medical products. To our knowledge, this is the first study of its kind in Sweden. Two Polish studies related to our study can be found.^{26,27} They showed that 88.2% of the physicians had faced a problem or heard of the SF medical products or dietary supplements phenomenon,²⁶ that 56.2% of the physicians usually do not warn patients about SF medical products²⁷ and that 66.9% did not know the procedure for reporting suspicious medicine.²⁷ Only 12 of 268 physicians had encountered complications caused by medicines from unknown sources.²⁷ However, the studies were conducted in different circumstances with a different design and did not have the same target group. Therefore, a direct comparison cannot be made but both Swedish and Polish physicians showed a need for further education in reporting SF medical products.

What this study adds?

This study adds knowledge about a lack of awareness about SF medical products and about the recommended reporting system among physicians working in the first line of healthcare, primary and emergency care. It points to a need for educational activities directed to physicians concerning this global public health threat.

Limitations of this study

This study is part of a larger project concerning SF medical products in Sweden and makes no comparisons between the groups of physicians.²² Its purpose is to be descriptive in the quantitative parts and present the physicians' experiences. The study prioritized obtaining a relatively large amount of answers, set at 100 from each group. Through the choice of method, there is possibility to generalize the result but some parts of the method limit the generalizability. The participants were randomized from TNS SIFO's medical database which according to TNS SIFO reflects the current situation.²⁴ Randomization promotes the generalizability of the study. Some conscious choices were made that limited the generalizability in order to obtain a rich material. Firstly, only the first 100 answers were included, which limited the effect of randomization. Secondly, for the EPs, specialists in emergency medicine and internal medicine were targeted to get a rich material since we assumed that these specialties had the highest rate of taking care of patients with diffuse symptoms. To obtain 100 answers, the targets were widened to nearby specialties. As a result, the composition of specialties in our EPs group is unlikely to be representative of the composition of all physicians working in emergency care.

As compared to figures from the Swedish National Board of Health and Welfare, the responding GPs had a slightly higher median age than the entire Swedish GP group (60 years vs. 56 years) and consisted of more male GPs (60% vs. 54%).²⁸ Older physicians may not be as well updated as younger persons on new phenomena such as ordering drugs online. That could distort the results and make the GPs appear less knowledgeable. There is no obvious reason to believe that gender should affect the result. Overall, we assess that the known overrepresentation should not affect the results in a major way. This kind of comparison could not be done with the EPs since the group consisted of physicians from a variety of specialties.

Conclusion

In this study in general practice and emergency care in Sweden, 78.5% of the physicians had heard about SF medical products and 36.5% had met patients they suspected had taken such medicines. The physicians lacked awareness of the use of the reporting system when they suspected SF medical products. To meet the Swedish Medical Products Agency's expected standard, the physicians need more knowledge and they are positive to more education.

We want to clearly state that the term used in the survey was 'illegal and falsified medicines' which was the concept used in Sweden at the time of our data collection. The WHO launch of the concept 'substandard and falsified medical products', shortened to SF medical products, covers what previously referred to in Sweden as 'illegal and falsified medicines'. Although there are still different opinions in the science community about the term of the WHO, we see great benefits and adhere to SF medical products.

The results of this study are being used in the larger project about SF medical products and can be used by authorities to know how to relate to this fast-evolving issue, to create educational material and as a basis for further studies.

Supplementary data

Supplementary data are available at the *Journal of Public Health* online.

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